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February 29, 2000

BY HAND DELIVERY

Dockets Management Branch
Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, MD 20857

Re: Docket No. 00P-0499/CP 1

The undersigned, on behalf of SmithKline Beecham Corporation ("SmithKline"), submits this preliminary response to the above-captioned citizen petition dated February 3, 2000, which was filed on behalf of Apotex, Inc., the TorPharm Division of Apotex, Inc., and Apotex Corporation (collectively, "Apotex"). In that petition, Apotex requests that FDA delist by February 29, 2000, two of the patents listed in the Orange Book in connection with SmithKline's NDA No. 20031. Apotex further requests that the Commissioner refuse to permit any activity with respect to the two SmithKline patents or any patent issued to SmithKline in the future that would delay FDA's review and approval of Apotex's ANDA No. 075-356.

The relief requested in Apotex's citizen petition is barred by the applicable statute and regulations, and the citizen petition must therefore be denied. Among other things, the regulations are clear that FDA will not involve itself substantively in patent disputes of the nature that Apotex presents in its citizen petition and will instead defer to the patent holder with respect to listing questions. *See* 21 C.F.R. § 314.53(f). The regulations also are clear that patents can be timely listed after approval of a new drug application regardless of whether one or more other patents had been granted and were listed when the application was approved; in fact, the regulations and statute require that such patents be listed. *See* 21 C.F.R. § 314.53(d)(3); 21 U.S.C. § 355(b)(1). FDA would act unlawfully, in violation of its own regulations and the statute, by granting the relief requested by Apotex. There is accordingly no basis for the petition and it should be denied.

SmithKline intends to respond more fully to the issues raised in the citizen petition during the customary six-month period for review and initial action on such petitions. Although Apotex requests that FDA rule on its citizen petition on an extremely expedited basis and designates February 29, 2000, as the date by which Apotex requests that FDA make its ruling, the citizen petition does not provide an adequate basis for requesting that FDA's review of the petition be expedited. Nor is there any reason given in the petition or of which SmithKline is

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aware why the February 29 date specified in the petition would be significant. Rather, the February 29, 2000, deadline by which relief is supposed to be granted appears to have been chosen arbitrarily.

SmithKline requests that FDA review and act on the citizen petition in the normal course, thereby providing SmithKline an adequate opportunity to respond more fully to the issues raised in the petition. If FDA decides to expedite its review of the citizen petition, SmithKline requests that FDA provide reasonable notice to SmithKline of the date on which the review will take place so that SmithKline has an opportunity to submit a timely response to the petition in advance of FDA's decision.

Respectfully submitted,

A handwritten signature in cursive script, appearing to read "Bruce N. Kuhlik".

Bruce N. Kuhlik

Counsel for SmithKline Beecham Corp.

cc: Hugh J. Moore, Esq.
Lord, Bissell & Brook